

### **III. REMARKS**

#### **Preliminary Remarks**

Claims 1 to 49 are pending of which claim 1 is independent. Claim 1 is amended to *inter alia* a formulation for topical use comprising herbal active ingredients and a base suitable for topical penetration of the skin and to insert the word "or". Claims 14 to 20 are amended to further define the base. Support for the claim amendments can be found throughout the specification as filed (see, for example, paragraphs [0012] to [0014]). Therefore, the applicant believes that no new matter is added.

Claims 21 to 49 were withdrawn as being directed to a non-elected inventions. The applicant reserves the right to file one or more divisional applications directed to non-elected subject matter.

The examiner indicated that the Abstract was not drafted with proper language. The applicant respectfully disagrees. However, solely to expedite prosecution, the applicant has deleted the original Abstract in its entirety and replaced it with one that is free of the examiner's objections.

This response is filed within the shortened statutory period for response, no fee due, and is accompanied by printouts of two internet archive pages. The applicant respectfully requests reconsideration and allowance of the present application.

#### **Patentability Remarks**

##### ***Rejections under 35 U.S.C. §112 –***

Claims 1 to 20 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. The applicant respectfully traverses in view of the preceding claim amendments and succeeding remarks.

Claim 1 is amended to insert the word "or" in between (a) and (b). The applicant respectfully submits that the formulation of claims 1 to 20 comprises herbal active ingredients (a) or (b) or (c).

The applicant respectfully submits that claims 1 to 20 are not indefinite and requests withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

*Rejection under 35 U.S.C. §102 –*

Claims 1 and 10 to 13 were rejected under 35 U.S.C. §102(b) as being anticipated by King Bio Natural Medicines, as evidenced by Dr. Frank J. King and the Internet Archive Wayback Machine. The applicant respectfully traverses in view of the preceding claim amendments and succeeding remarks.

According to the examiner, “King Bio Natural Medicines teaches a formulation, ‘911 Stress Control 2 oz Liquid’, comprising homeopathic preparation of *Bryonia Alba* and homeopathic preparations of *Bellis Perennis*, *Calendula Officinalis*, *Arnica Montana*, *Hypericum Perforatum* and *Aconitum Napellus*, wherein each ingredient is in equal volumes of 10X, 30X, and 100X potencies in a pure water base.” (official action, page 5, last full paragraph). In addition, the examiner asserts that the product appeared on the World Wide Web as early as February 23, 2002. Finally, the examiner cites a telephonic interview with Dr. King, in which Dr. King stated that the product was in public use, and for sale, in March 1990.

The applicant respectfully submits that the examiner has failed to establish conclusively that the same version of “911 Stress Control 2 oz Liquid” cited by the examiner actually appeared on the World Wide Web as early as February 23, 2002. The applicant searched for archived web pages containing the Universal Resource Locator (URL) <http://www.kingbio.com/onlinepharmacy.htm> using the Internet Archive Wayback Machine (<http://www.archive.org>) as cited by the examiner.

While the search results page obtained was essentially identical to that obtained and provided by the examiner, when the applicant clicked on the hyperlink for “Feb 23, 2002” (as specifically indicated by the examiner), the applicant did not find the same web page that the examiner downloaded on June 8, 2005 and enclosed in the pending official action. Instead, the applicant found an archived web page advertising “911 Stress Control” that was devoid of any listing of ingredients. When the applicant investigated this issue further by clicking on other search page hyperlinks, the applicant did not discover an archived web page containing a listing of ingredients until June 7, 2002 (see the enclosed archive pages). Therefore, there is no evidence that the same

product as presently claimed “appeared on the world wide web as early as February 23, 2002.”

At best, “911 Stress Control 2 oz Liquid” appeared on the World Wide Web no earlier than June 7, 2002, i.e., less than 1 year before the priority date of the present application (March 14, 2003). Therefore, claims 1 and 10 to 13 cannot be rejected under 35 U.S.C. §102(b) over the “911 Stress Control 2 oz Liquid”. The proffered testimony from the examiner’s telephonic interview of Dr. King is unsubstantiated by the facts and must be withdrawn.

Moreover, the formulation of claims 1 and 10 to 13 is an external topical analgesic pain relief product, while “911 Stress Control 2 oz Liquid” is an oral internal mental and emotional stress formula only. Topical pain relief products must be less diluted (and contain at least one molecule) to affect peripheral nerve endings than oral, internal, mental stress formulations.

The examiner confuses *allopathic* drugs which, generally have only one or a very limited number of claims and uses per drug, with *homeopathic* drugs which have literally hundreds of possible therapeutic indications per drug. Dr. King’s inclusion of 20 drugs in “911 Stress Control 2 oz Liquid” would have thousands of untested possibilities for labeling claims—some indications would be archaic, obsolete, nonexistent or therapeutically insignificant, less than placebo effect, and unpredictable. Furthermore, reliable literature shows that many of the “911 Stress Control 2 oz Liquid” ingredients are inimical, or antidoted, or incompatible with one another.

In other words, the applicant respectfully submits that King Bio Natural Medicines (as evidenced by Dr. Frank J. King and the Internet Archive Wayback Machine) cannot anticipate (either under 35 U.S.C. §§102(b) or (a)) claims 1 and 10 to 13 and request withdrawal of this rejection.

*Rejection under 35 U.S.C. §103 –*

Claims 1, 10 to 14, 19, and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over King Bio Natural Medicines in view of Diec *et al.* (U.S. Pat. No.

6,468,551). The applicant respectfully traverses in view of the preceding claim amendments and succeeding remarks.

According to the examiner, "the teachings of King Bio Natural Medicines teach the instantly claimed invention except for a gel base comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben." (official action, paragraph bridging pages 6 and 7). In addition, the examiner asserts "it would have been obvious . . . to modify the formulation taught by King Bio Natural Medicines by adding the instantly claimed ingredients because . . . Diec taught a gel comprising water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben that was useful in the making of cosmetic or dermatological preparations."

As indicated previously, the "911 Stress Control 2 oz Liquid" is as an oral drug for internal stress. The claimed formulation is for topical analgesic pain relief. King Bio Natural Medicines clearly lists the following indications for use: "For fast relief of nervous tension, minor anxieties, fearfulness, over-sensitivity; effective support during high pressure and stressful situations". These are all internal emotional-mental states. No mention is made of the unrelated category of external pain relief for pains, aches, bruises, inflammation, etc. It would not have been obvious to those of ordinary skill in the art of homeopathy to use an oral drug for topical pain relief.

In fact, those versed in homeopathy would have readily recognized that an oral drug would not have been effective for topical use because, for example, an effective topical homeopathic product requires a penetrating base such as an alcohol of either undiluted mother-tinctures or slightly diluted (e.g., 1X to 6X) drugs to deliver enough molecules across a hydrophobic lipid epidermal barrier to affect nerve endings. In contrast, the "911 Stress Control 2 oz Liquid" is in distilled water and does not contain alcohol or a penetrating carrier. Therefore, it is unable (or barely able) to penetrate the hydrophobic lipid epidermal barrier or even stay on the skin.

Furthermore, King Bio Natural Medicines uses 10X, 30X, and 100X potencies only in the "911 Stress Control 2 oz Liquid" product. By homeopathic definition, 1X is one part in 10 of the original mother tincture. To make 2X potency, 1 part of the 1X is then added to 9 parts of diluent, and so on to higher serial dilutions. At 24X, one

reaches Avogadro's number ( $6.023 \times 10^{23}$ ) and no further molecules of the starting original mother tincture drug remain. Most of the King Bio Natural Medicines' "911 Stress Control 2 oz Liquid" is above 24X (*i.e.*, 30X and 100X) so theoretically no molecules can be present to stimulate epidermal nerve endings. Even the 10X portion of King Bio Natural Medicines' formula will only have 1 part in 10 billion ( $10^{-10}$ ) of the original drug - evidence that the "911 Stress Control 2 oz Liquid" formula is intended for internal use only for emotional and mental functions (as the labeling describes). Such a formula could not be useful for external topical analgesia.

Diec *et al.* do not overcome the limitations of King Bio Natural Medicines' "911 Stress Control 2 oz Liquid". Diec *et al.* do not teach or reasonably suggest that an oral drug for internal stress can be modified as a topical analgesic pain relief. Diec *et al.* merely disclose topical microemulsion gels. Therefore, the applicant respectfully submits that claims 1, 10 to 14, 19, and 20 are not unpatentable over King Bio Natural Medicines in view of Diec *et al.* and requests withdrawal of this rejection.

U.S. Patent Application No.: 10/797,009

Inventor(s): Dreyer

Attorney Docket No.: 025803-00003

#### **IV. CONCLUSION**

In view of the amendments and remarks above, the applicant respectfully submits that this application is in condition for allowance and request favorable action thereon.

In the event that this response is not timely filed, the applicant hereby petitions for an appropriate extension of time. The fee for this extension, along with any additional fees that are required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 025803-00003.

Respectfully submitted,

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**Indications for use:** For fast relief of nervous tension, minor anxieties, fearfulness, over sensitivity; effective support during high pressure and stressful situations.

**Other helpful natural medicines:** Eye Stress • Good Mood Enhancer

**911 Stress Control Ingredients:** Aconitum Napellus · Apis Mellifica · Arnica Montana · Arsenicum Album · Belladonna · Bellis Perennis · Bryonia Alba · Calendula Officinalis · Chamomilla · Cistus Canadensis · Clematis Erecta · Ferrum Phosphoricum · Histaminum · Hypericum Perforatum · Ignatia Amara · Impatiens Glandulifera Flos · Ornithogalum Umbellatum · Passiflora Incarnata · Phosphorus · Prunus Cerasifera Flos · Rhus Toxicodendron · Sulphur · Symphytum Officinale · Veratrum Album. Each ingredient is in equal volumes of 10x, 30x, and 100x potencies in a pure water base.

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June 7, 2002

Indications for use: For fast relief of nervous tension, minor anxieties, fearfulness, over sensitivity; effective support during high pressure and stressful situations.

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February 23, 2002